

IV REMARKS

Claims 1-11, 13-15, 18-20 and 32-43 are pending. Claims 12 and 16-17 have been cancelled. Claims 1-11, 13-15 and 18-20 have been amended. Claims 32-43 have been added as new. Support new claims 33 and 35 can be found in the specification on page 29, lines 5-10. Support for new claim 34 can be found in the specification on page 27, lines 5-6. Support for new claims 36-38 can be found in the specification on page 21, line 22 through page 22, line 12. Support for new claims 39-40 can be found in the specification on page 27, lines 4-26. Support for new claim 41 can be found in the specification on page 17, lines 16-17. Support for new claim 42 can be found in the specification on page 25, line 26 through page 26, line 6 and support for new claim 43 can be found throughout the specification, but more specifically on page 9, line 22 through page 16, line 18 and page 31, lines 7-12. Applicants respectfully submit that no new matter has been added by virtue of this Amendment.

A. Double Patenting Rejection

In the Office Action, the Examiner rejected claims 1-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,106,865 and over claims 1-36 of U.S. Patent No. 6,395,303.

With regard to U.S. Patent No. 6,106,865, Applicants respectfully submit that the '865 patent does not claim or describe adding a sustained release carrier into the aqueous slurry as claimed in the present invention. Accordingly, claims 1-20 of the present invention are patentably distinct from claims 1-33 of the '865 patent. Therefore the Examiner's double patenting rejection in view of the '865 patent should be removed. As new claims 32-42 depend from amended claim 1 and new independent claim 43 also recites adding a sustained release carrier to the aqueous slurry, these claims are also patentably distinct from claims 1-33 of the '865 patent.

With regard to U.S. Patent No. 6,395,303, Applicants respectfully submit that the filing of a terminal disclaimer will be considered upon notification that the pending claims are otherwise allowable.

B. Rejection under 35 U.S.C. § 103(a)

In the Office Action, the Examiner rejected claims 1-20 under 35 U.S.C. § 103(a) as being unpatentable over the teachings of U.S. Patent No. 5,858,409 to Karetny *et al.*. The Examiner stated that Karetny “teaches a method of preparing spray-dried compressible granular formulation for preparing pharmaceutical tablets in which hydrolyzed cellulose or microcrystalline cellulose is used... compressed into pharmaceutical tablets, and conventional granulation and/or tableting additives such as surfactants (sodium lauryl sulfate), disintegrants and antiadherents/flow aids (colloidal silica) are added....”

Before addressing the Examiner’s rejection, a brief review of the invention is in order. Amended claim 1 is directed to “a process for the preparation of an agglomerated solid dosage form, comprising... preparing an aqueous slurry of (a) microcrystalline cellulose; (b) a microcrystalline cellulose compressibility augmenting agent ... (c) an active agent; and (d) an effective amount of a sustained release carrier; ... thereafter spray drying the resultant aqueous slurry... [to obtain] agglomerated particles which are directly compressible into a solid sustained release matrix which provides release of the active agent over a time period of about 8 to about 24 hours.”

New independent claim 43 is directed to “a process for the preparation of a sustained release agglomerated solid dosage form, comprising... preparing an aqueous slurry of (a) microcrystalline cellulose; (b) a microcrystalline cellulose compressibility augmenting agent comprising: (i) silicon dioxide; or (ii) a surfactant...; or (iii) a highly polar dye...; or (iv) a combination of two or more of (i), (ii) and (iii) above; (c) an active agent; and (d) an effective amount of a sustained release carrier; and ... thereafter spray drying the resultant aqueous slurry...

[to obtain] agglomerated particles which are directly compressible into a solid sustained release matrix which provides release of the active agent over a time period of about 8 to about 24 hours.”

Thus, in each of the independent claims of the present invention, the sustained release carrier is added to the aqueous slurry before spray drying (emphasis added).

In contrast, the Karetny patent does not teach or suggest a sustained release carrier, let alone a process wherein the sustained release carrier is added to the aqueous slurry before the spray drying step as claimed in amended independent claim 1 of the present invention. Karetny only describes a method for granulating pharmaceutically active agents by spray-drying an aqueous slurry of hydrolyzed cellulose (which is a type of microcrystalline cellulose) and a pharmaceutically active agent, wherein additional granulation and tableting additives, e.g., such as binders, fillers, disintegrants, flow aids, antiadherents and/or surfactants may also be present in the slurry (See the Karetny patent col. 3, lines 20-31). Accordingly, amended independent claim 1, and claims 2-11, 13-15, 18-20 and new claims 32-43 that depend therefrom, are not obvious in view of Karetny. As such, the Examiner’s rejection should be removed.

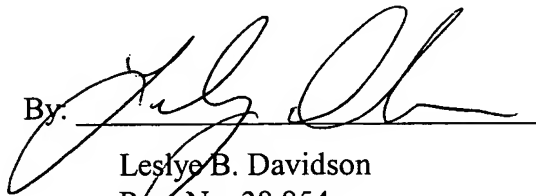
Applicants further point out that new independent claim 43 also recites, *inter alia*, adding the sustained release carrier to the aqueous slurry before the aqueous slurry is spray dried, and therefore, this claim also is not obvious in view of the Karetny patent.

V. CONCLUSION

Applicants respectfully submit that the present claims are in condition for allowance. An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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